

December 2nd 2002

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs

0039 0000000000

RE: Docket 00D-1539, 21 CFR Part 11 Draft Guidance (Sept 2000 ed.)
(herinafter, "Draft Guidance")

Dear FDA,

Thank you for the opportunity to comment on this draft guidance document. Overall, the Draft Guidance offered appears to be clear and helpful. But I have serious concerns with your so-called time capsule technique described in section 6.1, pages 12 and 13. First, the approach described in 6.1 is more accurately or more commonly known as mothballing. Second, the guidance totally omits any description of a genuine time capsule approach.

I

Section 6.1 of the Draft Guidance describes mothballing, not a time capsule. I do not believe that FDA has gone far enough to describe the pitfalls of mothballing.

- (1) It is the tendency of disk drives removed from active use, to be less and less likely to properly activate as the time from deactivation increases. In my experience, if a formerly daily-used unit has been out of service for 6 months there is perhaps a 50/50 chance it will reactivate. After a year successful reactivation is more a matter of hope than confidence. After two years, it is more a matter of luck than hope.
- (2) It is the nature of corporate computer techs to pilfer parts from obsolete and out-of-service units, to keep similar units still in service operating. I mean to cast no dispersion on any computer techs - it is simply a fact of business life that if a unit in service fails, and a unit that is out of service has a component that the immediate need requires, there goes the component. Measured again in the 6-month, 1-year and 2-year checkpoints, the odds are quite slim in a busy commercial or industrial environment, that a unit stowed away will have all its pieces when you go to use it 2 years later. I can say the same thing more or less, for the chances that all the boxes with all the pieces will still be together, if the monitor is in one box and the system unit for example, is in another.
- (3) Almost nothing changes faster than the networks we use. Yesterdays dedicated wiring is today's "ten base T" wiring is tomorrows cable or fiber or wireless network. Assuming as we

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must that no changes are going to be made to a mothballed system, as time goes on the chances that the old system will work on a modern network, sharply diminish.

- (4) One might think that preserving a printer with the mothballed system might solve the networking problem. But, it is the nature of ribbons to dry out, and for toner cartridges to harden up. And there just is no such thing as an interchangeable ribbon or cartridge. Note also, the very real possibility that the printer, ribbon or cartridge might be borrowed for use on an active system..

For all of these reasons, I strongly urge FDA to disclaim mothballing of any system containing live electronic records. (Or, any tape system or other proprietary-format back-up device that is needed to retrieve magnetically stored electronic records.)

The one occasion where mothballing makes sense is during the immediate aftermath of the time when the equipment is taken out of service, after all the live records have been theoretically extracted, to accommodate time for the quality assurance process that the extracted records will of course be going through. But in this case the mothballing should be no more than a month, and the equipment should be merely turned off, not dismantled.

II

Creating a genuine time capsule can be an excellent, highly secure and low-cost way to preserve electronic records that are needed for retention purposes, but have no other known business purpose. Note: For records that have continuing business vitality, the migration approach described in Sect 6.2 is probably the only practical approach. But if a system contains 100,000+ records dating back many years, it can be very practical to time-capsule the oldest years and only migrate the current records.

To create a time capsule we literally seal the records in plastic.

That is, we extract them in an external reporting format^{*1}, as if we have printed them, and then the "printouts" are copied onto a set of CD's. CD's (compact disks) are very widely available as are CD-burning devices and software. A modern CD holds well over half a gigabyte of formatted data, very securely and quite inexpensively.

But getting to all that raw data can be a problem if we do not think it through first. Ideally, one might either build an index of some sort at the same time as creating the files, or might use an

^{*1} text format, html format, pdf's or post script files, for example

"internet spider" to build an index after creating the documents, said index then being stored on the same CD with the records. For this purpose you might think about breaking your documents (records) into 500-megabyte chunks, leaving something over 200 megabytes available for the index. Another way to do it might be to use directory structures and aliases, for example records can be stored in customer folders by state and cross-referenced by aliases to product and lot number folders. *Creation of such an extract-conversion process would of course need to be validated and the results verified.*

The distinct advantage to the sealed-in-plastic time capsule approach, is security. Individual print-format files are very highly capable of being deleted, modified or tampered with if retained on magnetic media. But each CD produced these days is individually serial numbered. If each time capsule CD were to be individually certified by its creator and the person who verified the contents, there would be little doubt that a particular given CD was other than what it claimed to be.

We still have the "readily retrievable" requirement to think of. For best results, simply create multiple copies of each master CD and store them with different interested custodians. The data processing personnel that had original responsibility for the physical computer system can retain one copy. One copy might go to your local quality assurance or compliance unit, the people who perform the audit escort duty when FDA is on-site. Another copy could be created for each user department that had responsibility for the original record creation. So, to consider the accuracy of any particular CD or record, another copy of the CD can be obtained for comparison. Likewise, if a set is lost, one of the other sets can be used to create a perfect copy.

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In the end, I urge FDA to correctly describe the mothballing approach, and to strongly discourage mothballing in any context that would leave the mothballed system (and perhaps its proprietary backups) as the sole source of any original electronic records. And, I highly suggest that FDA should incorporate into the guidance some discussion of an approach to seal one's data into plastic and thus create a true time capsule.

Thank you for your attention,


Ray Miller